Senate Committee on Environment & Public Works

Hearing entitled, "Hearing on the Nominations of Michael Dourson, Matthew Leopold, David Ross, and William Wehrum to be Assistant Administrators of the Environmental Protection Agency, and Jeffery Baran to be a Member of the Nuclear Regulatory Commission."

October 4, 2017 Questions for the Record for Mr. Michael Dourson

Chairman Barrasso:

- 1. Are you familiar with the Pesticide Registration Improvement Act (PRIA)?
 - a. Do you believe the Act's provisions provide a predictable and effective evaluation process?

Yes, I have some familiarity with the PRIA. My understanding is that with the collection of fees EPA then has the resources to complete necessary scientific evaluations of pesticides in a defined and predictable timeline.

Ranking Member Carper:

- 2. For decades, both Republican and Democratic administrations alike have had written policies limiting White House contacts with agencies that have investigatory and enforcement responsibilities. These policies have recognized that even a simple phone call from the White House to an agency inquiring about or flagging a specific matter can upset the evenhanded application of the law. I recently learned that Devon Energy, a strong political supporter of Administrator Pruitt's, informed the EPA just 5 days after Mr. Pruitt was sworn in as Administrator that it was no longer willing to install air pollution technology or pay a high penalty to EPA for its illegal air emissions of cancer-causing benzene and other chemicals. We also know that Trump family casinos, hotels and golf courses have been the subject of EPA enforcement actions for violations of the Clean Air Act and Clean Water Act.
 - a. Do you agree that it is essential that in making decisions, EPA's OCSPP must be shielded from political influence and spared even the appearance of being subject to political influence or considerations?
 - If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.
 - b. Will you commit to restricting communications between OCSPP and the White House staff regarding specific matters under the authority of OCSPP?
 - If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.
 - c. Will you commit to ensuring the staff of OCSPP is familiar with those restrictions?
 - If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.
 - d. Will you commit to advising this Committee within one week if any inappropriate communications from White House staff to OCSPP staff, including you, occur?
 - If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

3. Recently, EPA conducted "anti-leaking" training for its employees¹. According to EPA sources, the briefing stated that "Prohibitions we will discuss do not refer to "Whistleblowing". Agency employees have the right to make lawful disclosures to anyone, including, for example, management officials, the Inspector General, and/or the Office of Special Counsel. Employees may make disclosures to the EPA Office of the Inspector General through the EPA OIG Hotline at 888-546-8740." This presentation evidently failed to note the rights of federal employees have to make disclosures to Congress.

5 U.S.C. § 7211, provides that: The right of employees, individually or collectively, to petition Congress or a Member of Congress or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied. Pursuant to 5 U.S.C. § 2302(b)(8), it is a violation of federal law to retaliate against whistleblowers. That law states: Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority ... take or fail to take, or threaten to take or fail to take, a personnel action with respect to any employee or applicant for employment because of. ... (A) any disclosure of information by an employee or applicant which the employee or applicant reasonably believes evidences- (i) a violation of any law, rule, or regulation, or (ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, any disclosure to the Special Counsel, or to the Inspector General of an agency or another employee designated by the head of the agency to receive such disclosures, of information which the employee or applicant reasonably believes evidences a violation of any law, rule, or regulation... " In addition, pursuant to 18 U.S.C. § 1505, it is against federal law to interfere with a Congressional inquiry: Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

a. If you are confirmed, will you commit to protect the rights of all career employees in OCSPP to make lawful disclosures, including their right to speak with Congress?

If confirmed, I commit to protecting the rights of OCSPP employees and will follow the law.

b. Will you commit to communicate employees' whistleblower rights via email to all OCSPP employees within a week of being sworn in?

If confirmed, I commit to protecting the rights of OCSPP employees and will follow the law.

4. Recently, EPA decided not to revoke all the remaining tolerances for chlorpyrifos as had been proposed by the Obama Administration.

 $^{^{1} \}underline{\text{https://www.washingtonpost.com/politics/whitehouse/federal-employees-are-ordered-to-attend-anti-leaking-classes/2017/09/21/032b40d6-9edd-11e7-b2a7-bc70b6f98089 story.html?utm term=.e2bfc5e54d95$

a. Do you believe that EPA should ever use epidemiological studies as a basis for the agency to conclude that it cannot make a determination that exposure to a substance can occur with a "reasonable certainty of no harm" under the Federal Food, Drug and Cosmetic Act (FFDCA)? If so, when? If not, please fully describe the reasons why not.

Epidemiology studies are an important part of any risk assessment and should be evaluated routinely as part of any risk management decision. I believe there will be situations where the use of epidemiological data is appropriate. This will depend on the quality of the epidemiological data and the specifics of the determination it informs.

b. One of the complicating factors surrounding the proposed Obama Administration's ban on the remaining uses of chlorpyrifos was the assertion made by some that there is uncertainty associated with the level of chlorpyrifos that causes an adverse health effect and debate about which biological endpoint should be used to define what an "adverse" health effect should be. If EPA cannot make a "reasonable certainty of no harm" finding under the FFDCA for a substance, how would you suggest EPA resolve such uncertainties in order to comply with both FFDCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)?

Scientific approaches exist to help quantify and understand the impacts of uncertainty on a decision. If confirmed, I would use these approaches and would additionally seek further data and information to inform decision making.

5. EPA currently uses a 10-fold safety factor to account for the added risks mutagenic carcinogenic chemicals pose to vulnerable sub-populations. Will you commit to continue this approach? If not, please provide a specific explanation for when, why and how you would deviate from this approach.

I am familiar with EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (March, 2005). If confirmed, I commit to using the best available science in considering any regulatory actions that come to me for decision making.

- 6. EPA often uses a safety adjustment factor when it writes rules that protect people from exposure to chemicals. That factor accounts for the interspecies variability between the effect of the chemical on an animal that is measured in laboratory tests and the predicted effect of the chemical on people.
 - a. If you are confirmed, will you commit to continue to support this approach?

Yes, when appropriate I will continue to use this approach.

b. If not, how would you propose to account for interspecies differences between a chemical's measured effect on an animal and its predicted effect on a human?

When sufficient data and understanding exists, physiologically based pharmacokinetic (PBPK) models can be used to inform the differences between animals and humans.

- 7. One argument that is often made to justify less protective chemical safety standards is to set an adverse effect end-point that is 'more adverse' than other end-points. For example, it would take higher exposure levels to a chemical for the chemical to actually cause cancer than it would for a biochemical marker that is a known precursor to cancer to be observed. Using cancer as the end-point in this scenario would allow for a less stringent safety standard for that chemical to be set.
 - a. Generally speaking, if there is an end-point that is a precursor or otherwise predictive of a serious illness or risk of acute toxicity, is there ever a scenario in which EPA should regulate to protect against the precursor end-point rather than the more serious one? If so, please describe such scenarios. If not, please fully explain why not.

There are scenarios where this is appropriate. It's use will depend on our understanding of the chemical's mechanism of action

b. Additionally, if it is your view that safety standards should not seek to prevent effects that are known to be predictive of more serious ones, please explain your views on whether the FDA should continue to approve cholesterol-lowering medications or whether it should simply focus its efforts on ways to better treat heart attacks. If you believe that preventive medicine should continue to be developed and approved, why are your views different for chemical safety standards?

The appropriate use of safety factors is determined by available data and our understanding of a chemical's mode of action. I do not have an opinion on FDA actions.

- 8. On February 28, 2017, President Trump directed EPA and the Army Corps to review and possibly rescind or repeal the Clean Water Rule in Executive Order 13776. EPA recently ended the public comment process on the first step of a two-step process to repeal the rule and replace it with a rule that will protect far fewer sources of drinking water. Individuals with first-hand knowledge of the process EPA utilized to prepare its have informed my staff that:
 - a) When EPA first submitted the proposed repeal rule to OMB, the draft stated that a the agency would undertake a new cost-benefit analysis as part of the second step of its process.

- b) OMB interpreted EPA's first proposal to mean that the rule's repeal would not avoid any costs to industry or have any economic impact at all. EPA's political staff then directed the career staff to undertake a new economic analysis. In response to this direction from OMB, EPA career staff reportedly changed the table included in the 2015 rule to i) reflect 2016 dollars instead of 2014 dollars, ii) convert "annual costs incurred" under the Clean Water Rule to "annual costs avoided" due to its repeal and iii) convert "annual benefits gained" under the Clean Water Rule to "annual benefits forgone" due to its repeal. This new table was sent to OMB on June 8, 2017.
- c) OMB correctly concluded from EPA's June 8 submittal that repealing the rule would cost more in lost benefits than it would save industry in compliance costs. On June 13, 2017, presumably to avoid such an admission on the part of EPA, EPA career staff were verbally directed by political staff to solve this 'problem' by simply deleting the majority of the benefits of the rule from the table and resubmitting it to OMB, which they did².

The direction that was reportedly provided to the EPA career staff to make the various revisions to what was submitted to OMB was verbal, not written. If you are confirmed, do you commit to ensure that career staff in OCSPP will receive appropriately documented, rather than verbal, direction from political officials before they take action? If not, why not?

I support the appropriate use of both written and oral guidance and would endeavor to use each in appropriate circumstances.

- 9. Thank you for your response to my pre-hearing questions. I have some follow-up questions. In the spreadsheet you provided that listed sponsors, project description and project type information, there are several entities that seem incorrect. For each of these, please explain the apparent discrepancy, and if any of these entries are errors, please submit a corrected version of the spreadsheet in excel format:
 - i. Several entries that list the American Chemistry Council as its sponsor as "collaborative" rather than "private sector;"

This designation is correct. The overall project was a collaboration of several organizations.

ii. Listing an entry in which the California Chamber of Commerce is the sponsor as "non-profit" rather than "private sector;

The non-profit designation is correct (see: https://www.calchamber.com/aboutus/Pages/default.aspx).

Page 6 of 42

² https://www.epa.gov/sites/production/files/2017-06/documents/economic analysis proposed step1 rule.pdf See Table 1

iii. Listing an entry in which the CEFIC is the sponsor as a "collaboration" rather than "private sector";

This designation is correct. The overall project was a collaboration of several organizations.

iv. Listing an entry in which Concurrent Technologies Corporation is the sponsor as "government" rather than "private sector";

This designation is correct. TERA was a subcontractor to CTC who was working for the government.

v. Listing an entry in which EPRI is the sponsor as a "collaboration" rather than "private sector";

This designation is correct. The overall project was a collaboration of several organizations.

vi. Listing an entry in which ICL-IP is the sponsor as a "collaboration" rather than "private sector";

This designation is correct. The overall project was a collaboration of several organizations.

vii. Listing an entry in which ILSI-NA is the sponsor as "non-profit" rather than "private sector";

This designation is correct. ILSI is a 501(c)(3) nonprofit organization.

viii. Listing an entry in which Lockheed Martin Corporation is the sponsor as "government" rather than "private sector";

This designation is correct. TERA was a subcontractor to CTC who was working for the government.

ix. Listing an entry in which McKenna, Long and Aldridge is the sponsor as "government" rather than "private sector";

Yes, this is a mistake. A corrected spreadsheet is attached. Thank you.

x. Listing an entry in which Silicones Environment Safety & Health Council is the sponsor as "non-profit" rather than "private sector";

Yes, this is a mistake. A corrected spreadsheet is attached. Thank you.

xi. Listing an entry in which Summit Technology is the sponsor as "government" rather than "private sector";

This designation is correct. TERA was working with Summit Toxicology and the National Library of Medicine on this task.

xii. Listing an entry in which ToxServices is the sponsor as "government" rather than "private sector";

This designation is correct. TERA was a subcontractor to CTC who was working for the government.

xiii. Listing an entry in which the Vinyl Acetate Council is the sponsor as a "collaboration" rather than "private sector"; and

This designation is correct. The overall project was a collaboration of several organizations.

xiv. Listing an entry in which Waste Management is the sponsor as a "collaboration" rather than "private sector".

This designation is correct. The overall project was a collaboration of several organizations.

b. Please identify the "multiple sponsors" listed for each entry on this spreadsheet and indicate the percentage of funding received from each sponsor.

Descriptions of all collaborative projects are a matter of public record, and can be found at websites associated with the Alliance for Risk Assessment (ARA) or Toxicology Excellence for Risk Assessment (TERA). I would be happy to direct your staff to the appropriate location if they have specific questions. Funding amounts are not specified, but sponsors who offer remuneration in excess of 2% of TERA income are designated at

http://www.tera.org/about/FundingSources.html.

c. Please describe the criteria you used to designate an entity as a "non-profit," how you defined "sponsor" and how you defined "project "type".

We generally use 501(c)(3) designations as nonprofits. "Sponsors" refer to any group that supports the mission of Toxicology Excellence for Risk Assessment (TERA) whether or not they also obtain a report or opinion. "Project type" generally refers to whether the remuneration is from a government or other nonprofit, or from a private entity.

d. In the "Summary of billed hours" table, there is no designation for government-sponsored work for TERA for 1995-2015. Could you provide a new table that includes this information?

This is possible, but would take more time than permitted in answering these questions, since individual records for each year would have to be reviewed.

e. In the spreadsheet that includes this chart, you seem to have calculated the percentage of work done by sector by counting the number of projects you classified as falling under each sector and dividing by the total number of projects listed.

This is not correct. Rather, the percentage of work in the "Summary of billed hours" spreadsheet entitled "Question 2-TERA Yearly Funding 1995-2015" is based on the amount of time devoted to either nonprofit or profit areas by year. Time spent in the "collaborative" sector of the spreadsheet entitled "Question 3-Project Database January 2010 to June 2015" is evenly divided into profit and nonprofit times of the "Question 2" spreadsheet.

This does not reflect relative funding for projects in each sector, however. Please provide a detailed breakdown of the percentage of total funding received for projects included in each sector, using the corrected version of the table requested in c.

Summaries of funding amounts per sector were not developed.

f. In the chart, the work on the Kids+Chemical Safety website is described as: "Develop a kids risk webpage, in part." The project is listed as a collaborative twice, once with the American Chemistry Council (ACC) as the sponsor and once with the Combined Federal Campaign (CFC) as the sponsor. Did the CFC hire or pay TERA to develop the website?

No.

If not, what was their specific sponsorship role?

Funding by CFC was through contributions from CFC to TERA, and TERA's decision to use this funding for the kids website.

If so, how long after ACC hired TERA to develop the website did CFC contribute?

Continuously.

What percentage of the costs of developing the website were paid for by the CFC?

Various funding amounts are not given per sponsoring groups.

Did the CFC itself fund the website, or was it donations through a CFC listing?

Donations were through a CFC listing.

If so, were these donations from the federal government?

Various funding amounts are not given per sponsoring groups. However, the ACC contribution was the major part of the initial sponsorship.

- 10. The following questions refer to the chart I used during the hearing (attached). For each chemical listed on this chart, please provide a complete description of:
 - a. The year(s) in which you, TERA or other TERA employees were funded to work on the chemical.

The chart below has a number of errors. Please see attachment 1.

- b. The name of the entity or entities that provided such funding, and the funding amount. If the activity was a collaboration, please list all collaborators as well as the amount of funding each collaborator contributed to the effort.
 - Please see attachment 1, but note that specific funding levels are not shown because summaries of this information were not developed. However, if funding is over 2% in any one year for any sponsor past 2010, this can be found through links to specific years at http://www.tera.org/about/FundingSources.html.
- c. The type of activity (risk assessment, peer review, research paper, presentation, litigation support, etc) that was funded and the deliverables provided to the sponsor.

Please see attachment 1.

Science for Sale		
Chemical & Known Harms	EVA/Agency Safe Level	Dourson "Safe" Level
1,4-Dioxane (Likely carcinogen)	0.35 ppb	1000x higher
1-Bromopropane (Neurotoxin)	0.3 – 10 ppm	2 – 67x higher
PFOA (Thyroid disruption)	.07 ppb	2,143x higher
TCE (Carcinogen)	2 μg/m³	1.5 – 15x higher
Perchlorate (Thyroid disruption)	0.7 μg/kg/day	8.6x higher
Chlorpyrifos (Neurotoxin)	.0017 – 0.3 μg/kg/day	33-5,882x higher
Alachlor degradates (Liver, kidney damage)	20 – 70 ppb	80 – 280x higher
Acetochlor degradates (Thyroid, reproductive disruption)	100 – 300 ppb	4.7 –14x higher
Diacetyl (Severe lung damage)	5 — 10 ppb	20 - 40x higher
Acrylamide (Neurotoxin, likely carcinogen)	.002 mg/kg/day	10 – 25x higher

11. Do you believe that there is a safe level of exposure to perchlorate for i) a pregnant woman, and ii) a toddler, with serious iodine deficiencies, and if so, what is it? Do you believe that there is a safe level of exposure to perchlorate for i) a pregnant woman, and ii) a toddler, who gets insufficient iodine according to World Health Organization guidelines, and if so, what is it?

If confirmed, I will evaluate chemicals under the statutory authorities granted by Congress to safeguard the public.

- 12. On September 21, 2017, the Consumer Product Safety Commission (CPSC) approved a petition³ that called for CPSC to write regulations requiring the removal of organohalogen flame retardants from four types of consumer products.
 - a. An argument against the petition is that EPA is currently reviewing flame retardants under TSCA. Do you agree that EPA is currently undertaking a risk evaluation on only the Cyclic Aliphatic Bromide Cluster flame retardants (i.e. only one class) and that EPA is required by law to complete this risk evaluation and finishing a regulation (if needed) by November 29, 2021?

I am aware that EPA is evaluating some flame retardants. I am unclear of the timeline.

³ http://earthjustice.org/sites/default/files/files/FHSA-Petition%20 revised 6-30-15.pdf

b. According to EPA's website⁴, "the hexabromocyclodecanes (HBCD cluster) in the cyclic aliphatic bromide cluster consists of the following chemicals:

Hexabromocyclododecane; 1,2,5,6,9,10-Hexabromocyclododecane; and 1,2,5,6Tetrabromocyclooctane. Two of these chemicals are used as flame retardants, no uses for 1,2,5,6-tetrabromocyclooctane have been identified. The primary use of the two chemicals is in expanded polystyrene foam (EPS) and extruded polystyrene foam (XPS) in the building and construction industry for thermal insulation boards and laminates for sheathing products. They are also used in plastics (additive) and textiles (back-coating). In the United States, the HBCD cluster was historically used as a flame retardant in the back coating of textiles; however, research and information gathering indicates that the HBCD cluster is no longer used in consumer textile applications outside of the automotive industry." Do you agree that this type of flame retardant is generally not used in consumer products such as children's products, furniture, mattresses and the casings surrounding electronics? If not, why not?

Beyond the details on the EPA webpage, I am not familiar with the different types of products that different flame retardants are used with. If confirmed, I can look into this.

13. Do you agree to provide complete, accurate and timely responses to requests for information submitted to you by *any* Member of the Environment and Public Works Committee? If not, why not?

Yes

14. Before the end of the last Administration, EPA proposed to ban some uses of three dangerous chemicals using its new Toxic Substances Control Act authority. TCE is a probable carcinogen that is found in drinking water all across the country. Accidental exposures to MC, which is used in paint and furniture strippers, has killed at least 56 people since 1980. And a second chemical used in paint strippers, NMP, is dangerous for pregnant women to be exposed to. Some have suggested that these bans should not be finalized, saying instead that EPA should study the uses of these chemicals for three more years before proposing a rule. Do you disagree that more exposures, more illnesses and maybe even more deaths would probably occur as a result of a three year delay in these proposed bans? If so, on what basis? If EPA has already determined that some uses of these chemicals are dangerous, how could one justify the extra time, taxpayer dollars and risk to human health that would occur by studying these same uses for three additional years instead of acting to finalize the bans now?

I am not sufficiently familiar with EPA's proposed bans to respond to these questions. If confirmed, I will seek a briefing on the status of these proposed bans and I commit to evaluating all the scientific evidence to inform EPA's decision.

⁴ https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaulation-cyclic-aliphatic-bromide-cluster-hbcd

15. Recently, EPA announced that Administrator Pruitt would be publishing brief summaries of his calendars biweekly, after dozens of Freedom of Information Act requests for this information as well as a March request by me and my colleagues that he do so. During the Obama Administration, the Administrator, regional Administrators and all those serving in confirmed roles published their calendars daily⁵. If you are confirmed, will you commit to publishing your calendars daily? If not, why not?

If confirmed, I will make my calendar available on a timely basis.

16. Section 26 of the newly enacted TSCA states that:

"(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS. — With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6."

Page 1 of Attachment 1 is an email sent by EPA on March 17, 2016, the substance of which was shared with the bipartisan and bicameral negotiators of the Toxic Substances Control Act. It states that EPA "just discovered a technical issue that will have significant policy implications for EPA's ongoing work under Section 6. As currently drafted, both Senate and House bills could frustrate EPA's ability to timely manage risks that have been (or may be) identified in our current Work Plan risk assessments." The email goes on to describe several risk assessments on chemical substances (TCE, NMP, MC and 1-BP) that had been completed or were near completion by EPA, and stated that "EPA is not looking at all the conditions of use for these chemicals. This approach, which might be characterized as a partial risk evaluation or partial safety determination, we see as simply not contemplated under the Senate and House bills. The section 6 structure in both bills would require EPA to assess a chemical in its entirety, based on all conditions of use - not just a subset of those uses." EPA then went on to state that if it were to move forward with rulemakings to restrict or ban some or all of these substances (which it has subsequently proposed to do), there would be some risk that the rules would be found to be inconsistent with the new statutory requirement to assess all conditions of use. EPA said that it would "welcome an opportunity to work with you on a drafting solution to this issue."

a. Do you agree with EPA's March 17, 2016 view that if it had moved forward with these partial risk evaluations and rulemakings absent explicit statutory authority to do so even though the risk evaluations had not considered all conditions of use, that EPA could have been sued for not complying with the law's requirements? If not, please provide specific reasons why not.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

Page 13 of 42

⁵ https://yosemite.epa.gov/opa/admpress.nsf/Calendars?OpenView

b. Pages 2 and 3 of Attachment 1 consist of April 2, 2016 Technical Assistance from EPA that was provided to the Senate on a drafting solution to address the problem identified by EPA on March 17, 2016. Do you agree that this language, which is also drafted as an amendment to Section 26, bears a close resemblance to the language that was enacted into law, and, like the enacted text, provides EPA with statutory authority to complete rulemakings on the chemical substances on which it completed risk assessments prior to the enactment of the new law even though the risk assessments were not undertaken for all conditions of use? If not, please provide specific reasons why not.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

- 17. The newly enacted TSCA, for new chemicals, states that:
 - "(e) REGULATION PENDING DEVELOPMENT OF INFORMATION.—(1)(A) If the Administrator determines that—
 - (i) the information available to the Administrator is insufficient to perrit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); or
 - (ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk fact—ors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use; or (II) such substance is or will be produced in substantial quantities, and such substance e—ither enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator shall issue an order, to take effect on the expiration of applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order."

Attachment 2 consists of a portion of EPA's Technical Assistance on an April 7, 2016 draft of Section 5 of TSCA that EPA provided to the Senate. Comment A7 provides EPA's views on section 5(e). This comment noted a change from previous drafts, observing that the draft allowed manufacture of a new chemical to proceed even if EPA did not have enough information to determine whether it posed an unreasonable risk. This is because the draft as written allowed for

manufacture to proceed if EPA either took steps to obtain sufficient information about the chemical substance (but before it received and evaluated that information) OR if it imposed a risk management order. EPA also suggested some edits to this draft to restore the "functionality of the prior draft," which ensured that manufacture could not proceed unless/until the information about the chemical substance was sufficient and EPA made the necessary risk determination, or in compliance with an EPA-issued order to protect against unreasonable risk under the conditions of use while the information was being developed. Do you agree that the statute requires EPA to issue an order to protect against an unreasonable risk a new chemical substance may pose under the conditions of use, either while information EPA needs to assess the chemical substance is developed, or if EPA determines that the substance may present an unreasonable risk under the conditions of use, or if such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

18. Section 5(f)(4) of TSCA states that:

"(4) TREATMENT OF NONCONFORMINGUSES.—Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking."

Attachment 3 is an April 9, 2016 email from EPA providing responses to questions on the April 7 draft included in Attachment 2. The email asks whether the removal of provisions 5(e)(4) and 5(f)(1)(C) in that draft would also remove EPA's requirement to consider whether to issue a Significant New Use Rule (SNUR) when it issued orders to a submitter of a pre-manufacturing notice (PMN) (and explain its decision if it chose not to do so). EPA responded in the affirmative. Do you agree that the enacted law retained the April 7 draft's requirement to consider whether to issue a Significant New Use Rule (SNUR) when EPA has issued an order to a submitter of a pre-manufacturing notice (PMN) (and explain its decision if it chooses not to do so)? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

19. The newly enacted TSCA requires EPA, for existing chemicals that are designated a high-priority chemical substance or otherwise designated for a risk evaluation, to:

"conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use."

In the statute, 'conditions of use' is defined as:

"the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

Attachment 4 is a December 12, 2016 (post-enactment) email conveying Technical Assistance from EPA that responded to several questions posed about how EPA was required to do risk evaluations for a chemical substance under the conditions of use. Do you agree with EPA's responses to these questions as well as the narrative that precedes the specific responses to questions? If not, please provide specific reasons why not, indicating in your response how your views are consistent with the statutory text excepted above (or, as applicable, how EPA's responses are inconsistent with the statutory text excepted above).

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

- 20. Attachment 5 is a document that includes EPA's technical assistance and observations that compared an April 12 2016 Senate draft of section 5 to an April 18, 2016 House draft.
 - a. On pages 2 and 15, EPA provides comments related to the 90-day period for review of a PMN. Do you agree that the enacted law includes text that reflects EPA's input in these comments? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

b. On Page 14, EPA notes the deletion of the requirement not to consider costs or other non-risk factors when considering section 5(h) exemption requests. Do you agree that the enacted law retained this deletion in this subsection, but included the requirement in sections 5(a), 5(e) and 5(f)? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

- 21. Attachment 6 consists of EPA's comments to a draft of Senate section 5 dated around April 12, 2016.
 - a. EPA's comment A22 notes the absence of the requirement not to consider costs or other non-risk factors when considering section 5(h) exemption requests. Do you agree that the enacted law does not include the requirement in this subsection, but does include the requirement in subsections 5(a), 5(e) and 5(f)? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

b. Do you agree that while this same EPA comment identifies one inconsistency between the above-described text that is absent from subsection 5(h) but appears throughout the rest of section 5, it does not identify another difference, namely the presence of the term "specific uses identified in the application" in subsection 5(h) versus the term "conditions of use" that appears throughout the rest of section 5? If not, why not?

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

- 22. Attachment 7 consists of EPA's comments to an April 3, 2016 Senate draft of section 5.
 - a. On page 1, EPA observes that "5(e) requires no action on the part of the Administrator whatsoever: it is wholly discretionary authority to impose requirements on the manufacture pending development of information." Do you agree that the enacted law requires EPA to either prohibit manufacture or issue an order to mitigate against potential risk while information is being developed by a manufacturer? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

b. On page 2, EPA responds to a question posed by Senate staff, stating "We think it is important not to limit review to the uses identified in the notice. If the identified uses seem fine, and EPA therefore does nothing, the submitter is free to submit an NOC and then manufacture in any way he or she wants. EPA often uses 5(e) orders to address uses beyond those specified in notices." Do you agree that the enacted statute requires EPA to review the conditions of use (as that term is defined in the statute) of a chemical substance when it reviews a PMN as EPA advised the Senate

in this comment? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

c. On page 9, EPA says that "It seems like the best solution, per above comment, may be to drop the limitation above that the order pertain only to the conditions of use specified in the notice." Do you agree that the enacted statute incorporated EPA's proposed 'best solution' and did not limit orders only to the conditions of use specified in the notice? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

d. A second EPA comment on page 9 states that "A possible solution would be, in line with the Senate bill and offer, to drop (e) and require EPA to issue an order under what is now (f) any time EPA either makes a may present finding or lacks sufficient info, as necessary to make the unlikely to present finding." Do you agree that the enacted text retains section 5(e) and also requires EPA to issue an order any time EPA either makes a may present finding or lacks sufficient information before manufacturing can commence? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

e. On page 16, EPA responds to a question from Senate staff about whether, in the 5(h) exemptions section, it makes sense to deviate from the rest of the section's references to 'conditions of use' and instead limit EPA's exemption determination to the uses of the chemical substance identified in the exemption request. EPA responds by stating "We agree that the reference to specific uses makes sense, but not because of anything having to do with a SNUR. It seems to us that, if a party is seeking a partial section 5 exemptions, we would consider only the uses for which they are seeking the exemption, since the exemption would limit them to those." Do you agree that the enacted statute follows EPA's advice to retain the authority for EPA to consider just the uses of a chemical substance included in an exemption request, but does not make the same limiting change anywhere else so as not to so limit its review of all conditions of use of a chemical substance subject to a PMN? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

23. In our private meeting, you described your work on perchlorate as an example where the safety standard you suggested at the time (2004) was based on older science, and said that at that time, you actually recommended a level that was more protective than the one industry was recommending.

Yes, TERA's self-published recommendation in 2004 was 500-fold lower than the original safe dose proposed by industry.

Isn't it true that in 2012, seven years after EPA recommended its drinking water reference dose for perchlorate, you wrote a paper⁶ that suggested the removal of the three-fold safety factor designed to protect pregnant women, which, if adopted, means the reference dose would be 8.6 times less protective than EPA's?

I am not certain of the paper to which you refer. However, in 2004, I coauthored a paper that judged a Reference Dose (RfD) to be 0.002 mg/kg-day based on infants. EPA later came out with a RfD of 0.0007 mg/kg-day based on adults. The TERA and EPA RfDs are less than 3-fold apart. A comparison of the underlying information for these values can be found at https://toxnet.nlm.nih.gov/newtoxnet/iter.htm.

⁶

 $[\]underline{\text{https://yosemite.epa.gov/sab/sabproduct.nsf/F18F2B7E826BC94085257AD00053024F/\$File/TERA+Perchlorate+W}\\ \text{hite+Paper+12-4-12.pdf}$

Senator Booker:

24. In your statement and testimony, as well as on TERA's website, you tout the peer review and expert panel services you provide. Based on materials posted on TERA's website, TERA has in fact frequently been contracted to convene and manage peer review and expert panels on specific issues or specific chemicals. In the great majority of such cases, TERA has then appointed you to serve on the panel, most often as Chair. Established procedures for third-party peer reviews call for an arms-length relationship between the panel convener/manager and the members of the panel, to avoid conflicts of interest. How is it not a conflict of interest for TERA employees to appoint you, their boss, to be a member of and to chair these panels?

When groups, including government groups, contract with TERA, they recognize that someone from TERA will chair and also manage the panel. TERA also ensures that any relationships that could create a conflict of interest or biases of panel members are disclosed.

25. You also tout TERA's vetting of panelists for potential conflicts of interest. Here again, TERA has in virtually every case found that your serving on and chairing these panels poses no conflicts of interest. How do you justify having TERA employees vetting you, their boss, for potential conflicts of interest?

It is not clear why I would have a conflict of interest. However, if there is a conflict of interest, it would always be disclosed.

26. TERA has routinely cleared you (and in some cases other panel members) of having any conflicts of interest even in cases where you or other TERA employees (or other panelists) have conducted work for the very same companies or trade associations who are paying TERA to convene a particular panel? How do you justify this practice?

I would need to understand better the specific situation you are referring to in order to answer this question.

27. You state in TERA slide presentations, "TERA follows the National Academy of Sciences (NAS) procedures for panel selection and conflict of interest." NAS defines a conflict of interest, in part, as "any financial or other interest which conflicts with the service of the individual because it 1) could significantly impair the individual's objectivity... The term 'conflict of interest' means something more than individual bias..." You have repeatedly served on and often chaired expert or peer review panels which TERA was paid by a company to convene and run. As the director of a company with a direct financial interest in the funding it is paid for running panels, and the possibility that future income to your company may be compromised if the panel makes recommendations counter to the interests of the company paying for the services, on what basis do you believe (and has TERA found) that your serving on those panels does not present a conflict of interest?

TERA not only follows NAS guidelines but also had a small hand in helping develop these same guidelines. TERA's mission is in running independent panels in part. All panelists are offered travel and stipend remuneration for their efforts. TERA employees are offered salary and travel expense (as needed). Again, EPA, NAS and others follow a similar practice of paying panel members.

Senator Capito:

28. EPA's Safer Choice program allows companies to add a Safer Choice logo to product labels. The Safer Choice logo informs consumers that the product uses only safest-in-class ingredients. Without imposing regulations, the program has provided incentives to companies to formulate safer products and to develop innovative new chemistries.

Will you support continuing this program at EPA?

I am not familiar with the details of how this program operates. If confirmed, I will seek to understand it and would then be willing to have a further discussion with you about this program.

Senator Cardin:

29. Before the end of the last Administration, EPA proposed to ban some uses of three dangerous chemicals using its new Toxic Substances Control Act authority. Trichloroethylene is a probable carcinogen that has been found in unsafe levels in household wells on Maryland's Eastern Shore. Accidental exposures to methylene chloride used in paint and furniture strippers has killed at least 56 people since 1980, including at least two Maryland residents. Exposure to a second chemical used in paint strippers, N-Methylpyrrolidone, is dangerous for pregnant women. If you are confirmed, do you commit to quickly finalize these rules and prohibit the uses of these chemicals?

If confirmed I commit to quickly getting briefed on the status of these rules so that I can better understand them and the prohibitions proposed.

Senator Duckworth:

30. The Environmental Protection Agency (EPA) has said that exposure to cancer -causing chemicals in childhood can be as much as ten times as likely to lead to cancer than the same exposure to the same chemical in an adult. EPA has specific policies in place to account for these differences when it sets safety standards for chemicals.

You have questioned these polices claiming in your papers that, "by about 6 months of age, children are usually not more sensitive to chemical toxicity than adults" and "we are not aware of reported cases of differential harm to infants or children from low levels of regulated chemicals, like pesticides or food additives." This research was funded by the American Chemistry Council and Croplife America.

If you are confirmed, do you commit to apply, and not to weaken, EPA's current policies that account for the greater sensitivity and risk children may have from chemical exposures?

If confirmed, I will apply EPA policies and guidance as they are appropriate and consistent with today's best available scientific evidence.

31. During your nomination hearing you stated that you will seek guidance from EPA ethics officials on whether or not you should recuse yourself from issues for which you have previously been engaged in. However, as a regulator you can and should use your own discretion on recusal.

Yes or no, if confirmed, will you promise to recuse yourself from any agency action that relates to petcoke?

I will rely on the guidance from EPA's ethics officials to determine any issues for which I am to be recused.

32. As you know Administrator Pruitt, like Secretary Zinke and former Secretary Price have spent millions of dollars combined flying on private jets across the country. This is a gross waste of taxpayer dollars.

Yes or no, as a taxpayer, do you approve of Administrator Pruitt's travel practices on the public dime, and will you commit to utilizing commercials flights in your position?

If confirmed, I will commit to utilizing commercial flights whenever they are practical and feasible. I am not familiar with Administrator Pruitt's travel practices so I cannot comment on them.

Senator Ernst:

- 33. As you know, reauthorization of the Pesticide Registration Improvement Act (PRIA), was passed by the House earlier this year and we have also reported it out of the Senate Agriculture Committee. However, even though it has broad bipartisan support, it is set to expire on December 8, 2017. What would be the impact to worker protection programs and also to the EPA if this successful program is not reauthorized?
 - My understanding is that if PRIA is not renewed, then EPA would lose a significant amount of funds that are currently used to conduct the daily operations, including pesticide reviews, in the Office of Pesticide Programs. It is also my understanding that significant, or perhaps all, grant funding that is used to support worker protection programs would no longer exist.
- 34. As you know, the EPA follows a risk-based model in registration of pesticides the gold standard for much of the world. How would you protect and defend the standard of risk-based rulemaking both domestically and on the international stage?
 - I would protect and defend a risk based rulemaking approach by educating our colleagues domestically and internationally about this approach. I would do this by showing them how a risk based approach relies on the strength of the scientific evidence (including information from human studies, animal studies, and in vitro toxicological evaluations) to make highly informed decisions. The work conducted by the Office of Pesticide Programs provides many high quality examples of risk based evaluations.

Senator Fischer:

35. After a registrant spends tens of millions of dollars (or \$100-200 m) on development, many millions on safety data, submits often times over one hundred studies on the safety of the product, AND goes through FQPA rulemaking (special examination of children's risks, aggregate risk assessment, etc.) - can EPA actually communicate to the public that this pesticide product will not result in any unreasonable effects to the environment and human health? The Federal Food, Drug and Cosmetic Act says food must be "safe" but EPA seems reluctant to say the word – how will you ensure that EPA appropriately defends Agency decisions?

Whether EPA can state that the pesticide product will not result in any unreasonable risk to the environment and human health will depend on the results of the tests that are conducted. If the tests are negative, or show that effects occur at levels significantly higher than levels that humans and the environment are exposed to, then we should be able to confidently say that unreasonable effects are not expected. By using high quality science, and analyzing and integrating it in an objective and transparent manner I will ensure that EPA is able to defend its decisions.

36. As you may know, agricultural innovation has been bottlenecked by the previous administration's systematic decline for proven, peer reviewed, sound science. This spring, I was pleased to see the EPA deny a petition to remove a safe and proven product, Chlorpyrifos from the market. However, more work needs to be done to provide greater certainty for applicators utilizing FIFRA approved products.

I continue to be concerned about NPDES permit requirements for the application of pesticides in or near water. NPDES permits are duplicative and do not add any additional environmental protection beyond those provided through the FIFRA process. To the contrary, NPDES permits negatively impact the ability to protect people from mosquitoes that can vector the Zika Virus and other viruses like West Nile, to control invasive aquatic plants that contribute to flooding, impede navigation and impact public safety, and many other important uses.

Dr. Dourson, should you be confirmed, will you uphold the rigorous FIFRA pesticide registration process and work with Congress to eliminate these costly and duplicative permits?

Yes.

Senator Markey:

37. Dr. Dourson, according to the EPA website, the EPA Office of Chemical Safety and Pollution Prevention's mission is to prevent the public and environment from potential risks from pesticides and toxic chemicals. Do you promise to uphold this mission and take into consideration all potential risks from chemical exposures when making decisions on protecting public health and the environment?

Yes.

38. Commercial and native bees and other pollinators play a key role in agriculture and natural ecosystems and are vital to our nation's food security, production, health, and economy. Pesticides, in particular insecticides, frequently kill these pollinators causing havoc for beekeepers and raising the alarm for environmentalists, who would like to see particular pesticides banned. What role do you think EPA should take in dealing with this issue that takes into account the various stakeholders interested in this issue?

EPA, working with all stakeholders, should seek to understand the impact of insecticides on pollinators and based on the science should regulate appropriately to ensure protection.

39. For over two decades, EPA has failed to perform routine consultations under the Endangered Species Act on regulatory actions involving pesticides. This failure has resulted in extensive litigation. What do you see as the problems in the consultation process and what will you do to fix them?

If confirmed, I will seek to further understand the existing process and work to improve it with the hopes of limiting future litigation.

40. For more than half a century, chlorpyrifos has been widely used as a pesticide on a variety of crops. In November 2016, the EPA released a revised human health risk assessment for chlorpyrifos confirming that there is no safe level of chlorpyrifos in drinking water and that exposure to the chemical can cause not only acute illness, but leads to many long term neurodevelopmental issues for children, including attention deficit, reduced IQ and damage to the nervous system. The 1996 Food Quality Protection Act (FPQA) requires EPA to protect children from unsafe exposures to pesticides and ensure with reasonable certainty that "no harm will result to infants and children from aggregate exposure" to pesticides. If this standard cannot be met, the pesticide must be banned. Under court order and after years of delay, the EPA recently issued a decision refusing to ban the pesticide. Please explain why the evidence created by the EPA in its revised health assessment was not sufficient to conclude this issue. How will you ensure that this credible scientific evaluation is incorporated into any revised look at this pesticide?

If confirmed, I will work to understand this issue completely and will ensure that all decisions are based on and driven by scientific evidence.

41. One of the most significant changes made to TSCA under the LCSA was the streamlined authority for EPA to require testing of chemicals by order. However, to our knowledge that authority has not yet been used in the 15 months since the law took effect.

Given the importance of testing to fill data gaps, which is critical to both prioritization and risk evaluation -- and fundamental to a "risk-based" system, please tell us your plans for using the section 4 testing authority and approach for filling data gaps for both prioritization and risk evaluation."

If confirmed, I will seek to better understand the Section 4 testing authority under TSCA. With this knowledge, I will work to ensure that it is appropriately used to help fill gaps for prioritization and risk evaluation.

42. The new law requires EPA to restrict new chemicals where the available data are insufficient to address their risks. How will you evaluate the adequacy of data in PMNs? What will you do to assure that new chemicals are adequately tested?

I will use a weight of the evidence approach that considers all scientific evidence and information to evaluate PMNs.

43. The industry has pressured EPA to accelerate the completion of the review period for PMNs in order to reduce the PMN backlog. What steps will you take to assure that EPA does not sacrifice the rigor and thoroughness of the review process in return for speed?

If confirmed, I will work closely with staff to completely understand the PMN review process to ensure its rigor and thoroughness.

44. EPA staff has pointed to several ways industry can improve the efficiency of the review process by filing more robust PMNs that anticipate and respond to the likely concerns of EPA reviewers. What will you do to motivate industry to file more complete and accurate PMNs?

If confirmed, I will work closely with staff to completely understand the PMN process. It seems to me that if industry had a better understanding of the EPA evaluation approach, it should incentivize them to provide more complete and accurate PMN submissions.

45. Do you agree that more transparency is needed so the public can understand what EPA is doing to protect public health and the environment in the PMN process? What specific steps will you take to increase transparency?

I agree that transparency is always helpful and that the government should always strive to be more transparent. If confirmed, I will evaluate all the programs within OCSPP to ensure that they are sufficiently transparent and understood by all stakeholders.

Senator Merkley:

46. Please summarize the identified hazards of chlorpyrifos, and any impacts chlorpyrifos has on the brains of developing children.

Chlorpyrifos is an organophosphate insecticide, acaricide and miticide used primarily to control foliage and soil-borne insect pests on a variety of food and feed crops. Chlorpyrifos can cause cholinesterase inhibition in humans at high enough doses; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death. EPA has historically regulated chlorpyrifos on that endpoint.

47. Please summarize the identified hazards of flame-retardants, and any links to cancer or endocrine disruption.

It would be inappropriate for me to prejudge the issue, if confirmed I will ensure that the issue is fully and fairly considered in a publicly transparent manner that is consistent with EPA's statutory authorities.

48. Please summarize the identified hazards of alachlor, and any links between alachlor and cancer.

It would be inappropriate for me to prejudge the issue, if confirmed I will ensure that the issue is fully and fairly considered in a publicly transparent manner that is consistent with EPA's statutory authorities.

49. Will you defer to EPA scientists and career staff on matters of science?

If confirmed, as a scientist myself, I will work very closely with EPA scientists and other career staff to work towards consensus based on transparent, objective evaluations of scientific evidence.

50. Do you believe it is important to seek balanced input from industry perspectives and environmental and public health perspectives?

Yes.

51. In a recent public disclosure of Administrator Pruitt's calendar of meetings, only about 2-3% of his meetings were with public health and environmental advocacy organizations, whereas over 25% of his meetings were with industry representatives. Do you believe this reflects fair and balanced input from public health and environmental advocacy organizations?

Without knowing the number and nature of requests Administrator Pruitt received, it is difficult to judge if this reflects appropriate balance.

52. What do you think is a fair and balanced ratio of input from public health and environmental advocacy organizations?

A fair and balanced ratio of input would mean accepting an equal percentage of meeting requests from all stakeholder groups.

53. Will you commit to a fair and balanced ratio of input from public health and environmental advocacy organizations?

Yes, to the extent that I can control this.

54. When you and I met in my office, I asked you which chemicals you thought made sense to take off the market, and when asked about asbestos specifically, you said "yes". While I appreciate your willingness to ban asbestos in commerce, what tools could EPA use to address legacy exposures to asbestos under TSCA, such as exposure to asbestos already in many homes across the country? Will you commit to using TSCA to ban asbestos?

Although it would be inappropriate for me to prejudge the issue, if confirmed I will ensure that the issue is fully and fairly considered in a publicly transparent manner that is consistent with EPA's statutory authorities.

Senator Sanders:

Climate Change

55. President Trump has suggested in the past that climate change is a hoax. Is the President correct? Is climate change a hoax?

I believe that climate change is real and human activity contributes to climate change.

56. Do you agree with the vast majority of scientists that the combustion of fossil fuels contributes to climate change?

I believe that climate change is real and human activity contributes to climate change.

57. After Hurricane Harvey, an Arkema Inc. chemical plant exploded due to power loss and flooding. The EPA recently delayed implementation of a rule that requires hazardous chemical facilities to improve how they assess risks and prepare for potential hazardous incidents. This rule also would have required certain facilities to coordinate with local emergency response teams to ensure readiness in the case of an industrial accident, and would have provided additional information to nearby residents regarding chemical hazards.

Do you agree that communities deserve to be informed about potential chemical hazards from chemical facilities like the Arkema plant? If not, why not?

I am not familiar with the existing statutes and regulations. If confirmed, I will look into this.

Do you agree that this EPA rule could have helped mitigate environmental and chemical hazards following the Arkema plant explosion? If not, why not?

I am not familiar with the EPA rule you are referring to. If confirmed, I will look into this.

Do you agree with the decision to delay implementation of this rule? If so, why?

I am not familiar with the EPA rule you are referring to. If confirmed, I will look into this.

If confirmed, how will you work to address climate change to prevent massive toxic chemical exposure during and after climate-fueled super storms?

I am not familiar with the impacts of climate-fueled super storms. If confirmed, I will look into this.

Past Career/Conflicts of Interest

58. The U.S. Geological Survey says that glyphosate, the active ingredient in Roundup that has been listed as a carcinogen by the World Health Organization, is present in 59 percent of our country's surface water. Recently unsealed court documents in a suit against Monsanto indicate that a senior EPA official colluded with Monsanto to suppress research into glyphosate's toxicity.

You represented Monsanto on multiple occasions during your time at Toxicology Excellence for Risk Assessment. If confirmed, how will you prevent inappropriate undue influence from regulated industries on EPA employees?

If confirmed, I will work with the Office of General Counsel to ensure that outside parties, including regulated industries do not unduly influence OCSPP.

59. There are over 86,000 unregulated and largely untested chemicals currently in use in the United States. Thousands of these chemicals are being linked to negative health impacts – including birth defects, cancer, and other problems. Given the massive funding cuts that President Trump has proposed for OCSPP, how do you plan to implement and enforce the recently updated Toxic Substances Control Act (TSCA) and expand the list of banned chemicals?

I am unfamiliar with the proposed budget.

60. As founder of the chemical consulting firm Toxicology Excellence for Risk Assessment, you represented Monsanto, DuPont Chemical, the Dow Chemical Company, the American Chemistry Council, American Cleaning Institute, and American Petroleum Institute. If confirmed, you will be in charge of making sure that companies like these comply with chemical safety regulations and conduct waste clean-ups.

As Assistant Administrator of OCSPP, would you have any active conflicts of interests with these companies? If so, will you commit to recuse yourself for the full course of any matter in which any of your former clients is a party? If not, why not?

If confirmed, I would work with the Office of General Counsel to ensure that I am avoiding any conflicts of interest. I will recuse myself based on their direction and advice.

61. How does your work history of representing the chemical industry qualify you to lead an Agency tasked with ensuring the health and safety of working people, their families, and the communities in which they live?

My work history, which includes over 10 years at EPA, has consistently focused on provided objective, transparent, and high quality evaluations of scientific evidence to inform public health. I believe this approach is fully consistent with conducting good science at the EPA.

62. Vermont has recently experienced unsafe levels of Perfluorooctanoic acid (PFOA) in ground water. In 2000, the state of West Virginia hired you on DuPont Chemical's recommendation to determine a safe level of PFOA in drinking water. Despite clear science showing that the chemical's negative impacts on residents of West Virginia, you recommended safety standards 150 times less stringent than the maximum safety level that DuPont Chemical itself determined and thousands of times less stringent than the level set by the EPA in 2016.

How and why did you come to such a radically lower standard than DuPont and the EPA regarding acceptable PFOA safety standards?

The DuPont standard was understood by me at the time to be a placeholder until a consensus group reviewed all of the science. I was one of 10 scientists on this consensus group, of which 5 were from government (3 of them from EPA). The 150 ppb represented a consensus judgment of these 10 scientists based on the best available information at that time.

The PFOA safety standard you recommended turned out to be wildly inaccurate. These kinds of mistakes negatively impact the health of millions of people throughout the country. Given these kinds of mistakes and scientific inaccuracies, how will you ensure that standards are based on the best available science? If confirmed, will you commit to adhering to the science, and not necessarily the best interests of your former clients?

If confirmed, I will ensure that EPA continues to use a systematic review approach that includes seeking all available scientific information, including the newest research, to inform objective decisions to protect public health. The scientific data should be the foundation of decision making in OCSPP.

Science

63. At the EPA, science provides the foundation for Agency policies, actions, and decisions made on behalf of the American people. What should the role of science be in the development of the EPA policies, rules, and regulations?

Science should be the backbone and foundation of EPA policies, rules, and regulations.

Most Pressing Challenges

64. In your opinion, what are the most pressing chemical safety challenges that deserve the attention of the EPA? If confirmed, what will you do at the EPA to address these challenges?

The most pressing challenges within OCSPP involve 1) ensuring that EPA has sufficient expertise to fully implement the Lautenberg amendments to TSCA in the timelines required by the statute and 2) ensuring that the pesticides program also has the expertise to meet all the pesticide registration and re-registration deadlines as required by PRIA.

Page **33** of **42**

65. Last year's revisions to TSCA banned states from issuing their own toxic substance regulations if they are more stringent than the EPA's regulations. How will you ensure states' rights are preserved when states like Vermont may want to protect the health of people in their states in a more stringent manner than the federal standards?

If confirmed, I will seek to better understand the Lautenberg amendments to TSCA and will work with states to help ensure public health protection in all 50 states in a manner that is consistent with the law.

Environmental Justice

66. If confirmed, how will you address growing environmental and economic justice issues associated with chemical safety and pollution prevention?

I will work with staff to make this determination if confirmed.

67. Over 160 environmental and health groups, including the American Academy of Pediatrics, Breast Cancer Action, the Center for Biological Diversity, Clean Water Action, Food and Water Watch, Friends of the Earth, the Institute of Neurotoxicology and Neurological Disorders, and Utility Workers Union of America, have raised serious concerns with your nomination on the grounds that you are not suited to protect individuals, families, and the environment from potential risks from pesticides and toxic chemicals.

If confirmed, will you commit to working with these environmental groups and Americans who are threatened by toxic chemical pollution to ensure that OCSPP works to achieve environmental and human health?

Yes.

Senator Whitehouse:

68. Do you agree that the tobacco industry manipulated and obfuscated scientific research into the dangers of smoking for decades. Why or why not?

I do not have firsthand knowledge to comment.

- 69. Your name comes up over 460 times in the tobacco industry documents made public as part of the Tobacco Master Settlement Agreement. Some of your emails are there corresponding with Phillip Morris over work they hired you to do. Even your business card and Articles of Incorporation for your organization TERA are there, in the files of RJ Reynolds with a handwritten note next to your bio that the document should be filed under "Consultants/Dourson."
 - a. Did y ou provide RJ Reynolds your business card and TERA's Articles of Incorporation?
 - No. As I recall, and as stated in public records, our total RJ Reynolds work was ~\$85 to copy some studies from work we were doing for EPA. Phillip Morris work was \$550.
 - b. Please provide, for the record, a full accounting of the work, including the amount of money accepted, from whom, and the scope of work, that you did for tobacco companies and the role you played in the campaign to hide the truth about the dangers of smoking.
 - TERA was not part of any campaign. Our work is a matter of public record, specifically a 2015 hearing of the U.S. House Committee on Science, Space, and Technology. Our total income from these sources is approximately \$13,000.
- 70. In the late 90s, TERA, the organization you founded, received funding from the Center for Indoor Air Research (CIAR) to study the effects of secondhand smoke. TERA's name pops up throughout the tobacco database.
 - a. Do you believe CIAR was a front group for the tobacco industry? Why or why not?

I am not aware of this.

b. How much money did you receive from CIAR and for what purposes?

Approximately \$6000 to study the absorption of nicotine and measure its breakdown products in urine.

c. When you undertook work for CIAR, were you aware that secondhand smoke was considered dangerous to your health?

At high enough concentrations any chemical is dangerous to our health. Cigarette smoke is particularly worrisome.

d. When you undertook work for CIAR, were you aware that in a December 9, 1999 <a href="mailto-emailto

No.

e. Have you done any pro bono work you've done for the tobacco industry? If so, please describe it.

No.

- 71. You are the co -author of a paper "Distribution of Exposure Concentrations and Doses for Constituents of Environmental Tobacco Smoke" that used data from the 16 Cities study to minimize the effects of workplace secondhand smoke.
 - a. Are you aware that a 1992 EPA report identified secondhand smoke as a human carcinogen and the 16 Cities study was specifically conceived and designed to challenge this finding?

No.

b. When you used the data from the 16 Cities study, were you aware that its experiments and laboratory analyses were designed and carried out by R.J. Reynolds Tobacco Company scientists and that this level of involvement was not properly disclosed when the work was published?

Not that I recall.

c. The methodology used in the 16 Cities study has been criticized for inappropriately combining exposure data collected from workplaces that allowed smoking anywhere and those that allowed it only in designated areas to skew the results. Do you stand by the 16 Cities study methodology and data? Why or why not?

I would have to review these criticisms before taking a stand. However, I stand by the work we did as part of this paper. d. Your paper minimizes the impact of workplace secondhand smoke base d on the 16 Cities data. Do you stand by the findings of your report? Why or why not?

My interpretation of this study, or at least our part of this study, is different than your question.

e. Do you acknowledge that the 16 Cities study used data from wo rkplaces where few cigarettes were observed, while characterizing these environments as "smoking," with the goal of diluting their estimates of workplace secondhand smoke?

I do not know.

f. Are you aware that recent research using 16 Cities data comes to a conclusion that directly contradicts the findings of both the 16 Cities study and your own?

No.

- 72. According to an analysis by Environmental Defense Fund, the journal *Regulatory Toxicology* and *Pharmacology* has published 37 of the 66 studies you have co—authored since 1995, including many for which you or TERA received financial support from corporations and trade groups, including Procter & Gamble, Dow AgroSciences, and the American Chemistry Council. Additionally, you sit on the journal's editorial board. *Regulatory Toxicology and Pharmacology* has been widely criticized for its record of publishing industry-funded studies that were favorable to Big Tobacco. The journal editor, Gio Gori, has extensive ties to Big Tobacco.
 - a. Please provide the date range(s) during which you served as the president of TERA, all financial contributions received by TERA during that time, and resulting publications.

I served as TERA president from February of 1995 to August 2015. A yearly summary of remuneration can be found in TERA's submitted 990s. Many of the publications and reports resulting from this work can be found at www.tera.org, and related websites linked to this website.

b. Please provide a list of all studies you've published in *Regulatory Toxicology and Pharmacology* and who financed those studies.

Please see attachment 2.

c. Please provide the date range(s) for which you've been a member of *Regulatory Toxicology and Pharmacology's* editorial board, a list of all studies you've reviewed, and a list of all the funding for each of those studies.

I joined the board in the 1995. I generally review 4 manuscripts a year for this journal on a probono basis. I do not keep records of my reviews.

d. How many studies published in *Regulatory Toxicology and Pharmacology* have been financed by the tobacco industry?

I do not know.

e. Do you stand by the papers published in *Regulatory Toxicology and Pharmacology* with regards to risks associated with tobacco?

I am not aware of such papers, other than the one I coauthored.

73. In 2002, more than 40 health experts from government, academia, and environmental groups wrote to the *Regulatory Toxicology and Pharmacology's* editors to express concern over the clear conflicts of interest and lack of editorial independence. Do you believe *Regulatory Toxicology and Pharmacology* is free of conflicts of interest? If not, please describe the conflicts of interest of which you are aware.

Yes. As shown in Attachment 2, a large part of my papers were supported by governments, TERA, or the University of Cincinnati, College of Medicine. My most cited papers were published as an employee of EPA. However, most government work is not published in peer review literature. Rather, it forms the basis of government reports.

74. The Texas Commission on Environmental Quality (TCEQ) is the primary enforcer of the Clean Air Act in Texas. The TCEQ gave your organization, TERA, a four -year, \$600,000 contract to help review the agency's chemical evaluations. Two -thirds of these TCEQ analysis have made the guidelines less protective than they used to be. Specifically, TERA endorsed TCEQ values for the known carcinogens arsenic and hexavalent chromium that were much looser than those used in California or by the EPA. Please provide, f or the record, a full accounting of the work you did for the TCEQ including the financial sponsors of this work?

Generally, the work I conducted was based on more recent science or a larger set of data The work we did for TCEQ is a matter of public record . We had no other financial sponsors for the TCEQ work.

75. Michael Honeycutt sits on the steering committee for the Alliance for Risk Assessment, which is an affiliate of TERA. Mr. Honeycutt also heads the toxicology division at the Texas Commission on Environmental Quality (TCEQ). Although you have claimed that the Alliance is an independent entity, you have remained on its steering committee since its inception in 2007.

The Alliance is sponsored by TCEQ, Georgia Pacific, and the American Petroleum Institut e, to name a few. Yet, TERA's nonprofit tax filings don't include anything on the Alliance.

- a. How can you explain the significant conflict of interest presented by Mr. Honeycutt routing taxpayer dollars toward a firm whose decisions Honeycutt influences?
 - Dr. Honeycutt's participation on the Alliance for Risk Assessment (ARA) Steering Committee consists of review and endorsement of non-TCEQ projects. He recuses himself on TCEQ projects. The suggested Conflict of Interest (COI) in this question does not exist.
- b. Can you provide a full accounting of the work conducted by the Alliance for Risk Assessment and its financial sponsorships?

The ARA work and its sponsors are, and have been, publicly available.

76. In implementing TSCA, do you believe risk management costs should be considered when assessing whether a chemical poses an unreasonable risk?

The Lautenberg amendments to TSCA do not allow for the consideration of non-risk factors when making a finding of unreasonable risk. As such, risk management costs should not be considered.

77. In implementing TSCA, EPA, consistent with congressional intent, issued a notice making it clear that substantiation of all non-exempt confidential business information (CBI) claims is required upfront. Do you commit to ensuring the EPA follows and upholds that requirement?

Yes

- 78. Pursuant to the overhauled TSCA, EPA recently published its first inventory of mercury supply, use, and trade in the U.S., which have very little information because it did not benefit from the new reporting requirements. TSCA requires that EPA promulgate a mercury and mercury compound reporting rule by June 22, 2018 to assist in preparation of the inventory, the next one of which is required to be published by April 1, 2020.
 - a. Do you commit to completing the mercury and mercury compounds reporting rule by the June 22, 2018 deadline?

I do not know the status of this rulemaking within the Agency. However, if confirmed I will work to make sure that the TSCA deadline for this rule can be met.

b. Do you commit to identifying any manufacturing processes or products that intentionally add mercury or mercury compounds and recommend actions to achieve further reductions in such mercury use in the next inventory and publish that inventory by the April 1, 2020 deadline?

As noted above, I do not know the status of these activities within the Agency. If confirmed, I will work to understand their status and to ensure that EPA is meeting the deadlines required by the Lautenberg amendments to TSCA.

79. Mercury was on the 2012 Workplan Chemical List, but was removed from the list in 2014 because EPA already knew how highly toxic mercury is, and the Agency indicated it would be undertaking activities to implement the Minamata Convention on Mercury anyway. Significantly, this action was taken well before the revised TSCA was enacted. Under the revised law, to facilitate meeting its Convention obligations to reduce mercury use in the production of switches and switches, the phase down of mercury use in polyurethane production, and to regulate mercury use in new products and processes, it may be necessary for EPA to identify mercury among the next round of chemicals prioritized for action under TSCA. Will you include mercury among the next round of chemicals prioritized for action under TSCA as needed to further reduce mercury use in products and processes, and meet our obligations under the Minamata Convention?

I am not familiar with why mercury was removed from the 2014 workplan list. If confirmed, I will look into this and seek to ensure that EPA is taking necessary steps to further reduce mercury use in products and processes.

80. Administrator Pruitt has been criticized for spending a disproportionate amount of his time meeting with industry and virtually no time with public-interest groups. If confirmed, will you commit to meet with and listen to all parties in a balanced fashion?

Yes.

81. How should the EPA consider the synergistic effects of chemicals when considering approval of these chemicals under FIFRA?

I am not familiar with how synergistic effects are evaluated currently in the pesticides program. If confirmed, I will seek to understand this to ensure that EPA's approach is appropriate.

82. The Fish and Wildlife Service recently listed the rusty patched bumble bee as endangered, the first wild bee in the lower 48 states to receive this distinction. Pesticides were listed as part of the blame for the bee's current status. Other bumble bee species are also at risk due to increased pesticide use and other environmental challenges. How can the EPA assist in bettering the understanding of pesticides' role in declining bee and other pollinator species?

If confirmed, I will make sure that the impact of pesticides on bee populations is appropriately evaluated. I would work to ensure that the current testing requirements are adequate to ensure appropriate safety.

83. Under your leadership, what role will EPA play in the management and control of vector borne illnesses like Zika?

If confirmed, under my leadership, I will work to ensure that the Office of Pesticides Programs is actively engaged in reviewing the registrations of new pesticide products that can help decrease the spread and existence of Zika.

84. If confirmed, do you commit to notifying the Committee of all of the email addresses you plan to use upon confirmation and within seven days of using a new email address, including any aliases or pseudonyms? Do you commit do conducting all business using official email addresses and other means and to refrain from any mediums that are outside the Freedom of Information Act's reach?

Yes.

85. Do you a believe that climate change is real?

Yes.

86. EPA Administrator Pruitt recently told CNBC that "I would not agree that [carbon dioxide's] a primary contributor to the global warming that we see." Based on the scientific findings from experts such as NOAA and statements on EPA's website, including "Carbon dioxide is the primary greenhouse gas that is contributing to recent climate change," Politifact determined that statement to be false. Do you agree with Administrator Pruitt or scientific experts regarding whether carbon dioxide is the primary greenhouse gas that is contributing to climate change?

Climate science is outside my area of expertise and I would need further information before responding to this question.

87. In 2009, as mandated by the Supreme Court and backed by a robust scientific and technical review, the Environmental Protection Agency produced the Endangerment and Cause or Contribute Findings for Greenhouse Gases (GHGs) under Section 202(a) of the Clean Air Act. It found six greenhouse gases - carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride - "taken in combination endanger both the public health and the public welfare of current and future generations." Do you agree with the EPA's endangerment finding? Why or why not?

I am not familiar with the details of EPA's endangerment finding and would need to do more research on the topic before answering this question.

88. Do you believe hydrofluorocarbons are greenhouse gases? What is the global warming potential of methane, and from what source does that number come?

I am not sufficiently familiar with the definition of greenhouse gases and do not have the expertise to answer these questions.

89. Do you support the amendment to the Montreal Protocol to phase down HFCs?

I am not familiar with this aspect of the Montreal Protocol and thus cannot answer this question.

90. Do you believe the U.S. should remain a party to the United Nations Framework Convention on Climate Change?

Climate science is outside my area of expertise and I would need further information before responding to this question.

91. Do you believe the U.S. should remain a party to the Paris Agreement?

Climate science is outside my area of expertise and I would need further information before responding to this question.

92. If confirmed, do you commit to providing complete and accurate responses to inquiries from EPW members in a timely fashion?

Yes.